Significant Analysis
for Rule Concerning Automated Drug Distribution Devices
WAC 246-872

Briefly describe the proposed rule.

Hospitals and other healthcare facilities have purchased automated drug distribution devices to store and distribute medications in a secure manner outside a pharmacy and to improve access to medications for administration to a patient. The devices also better ensure that each patient is charge appropriately and provides accountability for each unit of medication.

The proposed rule will create a new chapter in WAC 246 and will adopt uniform standards for the use of automated drug distribution devices for those facilities that choose to use them. In addition, the proposed rules will include current Board of Pharmacy requirements for drug storage, security, and accountability. It will recognize the automated drug distribution device as an appropriate storage site for controlled substances.

The current rule applies to mechanical devices that are no longer available. For the few devices in use, the mechanical device rule will remain in place.

Is a Significant Analysis required for this rule?

The proposed rule makes significant changes to the existing rules. It applies to hospitals and other care facilities while the old rule is under retail pharmacy licensing. It is applicable to current pharmacy practice while the current rule applies to pharmacy practices of decades ago. The current rule limits all tasks to the pharmacist. In current practice the pharmacist often uses ancillary personnel for automated drug distribution device tasks. The current rule is titled "Mechanical devices in hospitals". The automated drug distribution devices are used in settings other than hospitals.

A new section in WAC 246 allows the proposed rule to accommodate all the settings that choose to use automated drug distribution devices. In addition, the Board of Pharmacy also wanted a separate chapter for the regulation of devices.

The proposed rule does not subject violators to a new penalty or sanction. Any penalties or sanctions levied for inadequate medication safety or accountability would be the same as for non-automated medication storage. The automated devices are able to reduce the risks of adequate medication safety and inadequate accountability through their enhanced reporting capability.

A. Clearly state in detail the general goals and specific objectives of the statute that the rule implements.

RCW 18.64.005(7) requires that the Board of Pharmacy adopt rules for the dispensing, distribution, wholesaling, and manufacturing of drug and devices and the practice of pharmacy for the protection and promotion of the public health, safety, and welfare. The proposed rule provides specific standards to improve medication safety, appropriate access to medications, and accountability, particularly for controlled substances.

B. Determine that the rule is needed to achieve these goals and objectives, and analyze alternatives to rulemaking and the consequences of not adopting the rule.

Hospitals and other facilities have voluntarily purchased automated drug distribution devices to store medications in patient care areas. Our current regulations do not apply to this method of medication storage to ensure medication safety, appropriate access to medications, and accountability, particularly for controlled substances. Without rule language there would not be enforceable standards that would apply to this method of medication storage. The automated drug distribution devices store and account for controlled substances in a completely different manner than the traditional locked cabinet, for example.

C. Determine that the probable benefits of the rule are greater than its probable costs, taking into account both the qualitative and quantitative benefits and costs and the specific directives of the statute being implemented.

The rule defines the requirements for automated drug distribution devices for hospitals and other facilities. The requirements in the proposed rule were developed by pharmacists and nurses in these facilities, as they want the requirements defined in a workable manner.

The benefits for those choosing to use automated devices include a basic clear expectation and a designed balance between medication accountability and ease of access by health practitioners. The rule is also designed to state responsibilities and allow facility management and the responsible pharmacist to determine how to satisfy the requirements.

The costs to the hospital and other health care facilities include staff time to develop policies and procedures for the use of the automated devices and training staff. These costs exist without the development of the rule and most facilities would incorporate similar requirements to comply with existing medication security and accountability requirements of the Board. Some facilities will run more reports to comply with the proposed rule. After thorough review of these rules, the Department has determined that the benefits outweigh the probable costs.

D. Determine, after considering alternative versions of the rule, that the rule being adopted is the least burdensome alternative for those required to comply with it that will achieve the general goals and specific objectives stated previously.

Program staff worked closely with pharmacists and nurses and the public to minimize the burden of this rule. Consideration was given to access to medications as well as restrictions. Requirements determined as unnecessary for the rule were eliminated based upon the input of the participants. The following alternative version(s) of the rule was considered but rejected:

(1) *Alternative version #1:*

Would have required the licensed health care facility to report device malfunctions to the pharmacy.

Compared to this alternative version, the proposed rule is less burdensome for those required to comply with it because the responsibility of reporting malfunctions to the pharmacy is not currently required for other types of medication storage and would place an unnecessary burden upon the licensee.

E. Determine that the rule does not require those to whom it applies to take an action that violates requirements of another federal or state law.

The rule does not require those to whom it applies to take an action that violates requirements of federal or state law.

F. Determine that the rule does not impose more stringent performance requirements on private entities than on public entities unless required to do so by federal or state law.

The rule does not impose more stringent performance requirements on private entities than on public entities.

G. Determine if the rule differs from any federal regulation or statute applicable to the same activity or subject matter and, if so, determine that the difference is justified by an explicit state statute or by substantial evidence that the difference is necessary.

The rule does differ from federal regulation or statute which have traditionally required end of shift controlled substances accountability. That difference is justified by the perpetual inventory capability of the automated drug distribution devices. The Drug Enforcement Administration recognizes perpetual controlled substances inventory and follows state regulation in supporting controlled substances regulation that includes perpetual inventory.

H. Demonstrate that the rule has been coordinated, to the maximum extent practicable, with other federal, state, and local laws applicable to the same activity or subject matter.

There are no other applicable laws.